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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NATNITHITHADHA, NAVIN	

ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,348	AYGEN, SITKE	
	Examiner	Art Unit	
	NAVIN NATNITHITHADHA	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see Remarks, p. 2, filed 09 September 2009, with respect to the rejection of claims claims 3-5 under 35 U.S.C. 101 as being directed to non-statutory subject matter, have been fully considered, and are not persuasive.

Applicant contends, see Remarks, p. 2, the following:

> The rejection cannot be maintained because it relies on overtumed case law, specifically the line of Federal Circuit decisions most recently the decision *In re Bilski,* 88 USPQ2d 1385 (Fed. Cir. 2008). The United States Supreme Court has just ruled that the Federal Circuit test for method or process claims, as held in the Federal Circuit Bilski decision, is not the exclusive test to determine satisfaction of § 101. *Bilski v. Kappos,* __ U.S. ___ (2010). In Bilski, the Supreme Court found that the machine-or-transformation test is not the sole test for patent-eligibility of process claims under § 101.
>
> Additionally applicant incorporates by reference, herein, applicant's remarks traversing the § 101 rejection in applicant's previously filed response.

However, this argument is not persuasive because Claims 3-5 neither transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to a particular machine. The claims do not past the "machine-or-transformation test" because they are not tied to a particular machine or apparatus (no machine or apparatus is recited) or does not particularly transform a particular article to a different state or thing (no transformation of a particular article is recited). The claimed method steps recites a transformation that involves only a change in position or location of an article and the article is merely a general concept, i.e. human behavior ("orally administering...") and mental activity ("determining $^{13}CO_2$ content...").

2. Applicant's arguments, see Remarks, p. 3, filed 12 July 2010, with respect to the rejection of claim 3 under 35 U.S.C. 103(a) as being unpatentable over Ben-Oren et al, U.S. Patent No. 7,338,444 B2 ("Ben-Oren"), in view of Katzman et al, U.S. Patent No. 6,186,958 B1 ("Katzman"), and the rejection of claims 4 and 5 under 35 U.S.C. 103(a) as being unpatentable over Ben-Oren in view of Katzman, as applied to claim 3, and further in view of Ghoos, GB 2360845 A ("Ghoos"), have been fully considered, but they are not persuasive.

Applicant contends, see Remarks, p. 3, the following:

> Katzman discloses an apparatus for detecting isotope ratios in the breath of a patient. The apparatus is small and can be used in a physician's office, but its use in a physician's office is not necessary (i.e., not required) according to the reference.
>
> Column 2 of Katzman discloses several applications of the apparatus invention (see items (a) to (j)). No specific test conditions for gastric emptying (item (g)) are described. Assuming a person skilled in the art would consider to use the Katzman apparatus for detection in the method of Ben-Oren, there is no teaching or suggestion in Katzman to exclude from the method of Ben-Oren the body-related factors required by Ben-Oren. In other words, combining the teachings of Ben-Oren and Katzman would, still, have lead the skilled artisan to use the "body-related conversion factors." When combining prior separate prior art references the PTO cannot pick-and-choose only those parts of the references that support a given position to the exclusion of other parts of the references necessary to understand what the reference teaches. Moreover, the mere absence of a negative (exclusionary) teaching from a reference neither teaches nor suggests the negative/exclusionary teaching. Alleged knowledge of one skilled in the art does not justify reading into a reference teachings that simply are not there.

However, this argument is not persuasive. Based on broadest reasonable interpretation, Ben-Oren teaches the limitation "wherein body-related conversion factors are dispensed with. Ben-Oren does not disclose using body-related conversion factors for any of the claimed steps.

In addition, Applicant's statement that "...combining the teachings of Ben-Oren and Katzman would, still, have lead the skilled artisan to use the 'body-related conversion factors'" is not persuasive because it is not supported by any evidence.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 3-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim(s) 3-5 are rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter because these claims are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to a particular machine. *See Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). *See also In re Bilski* , 545 F.3d 943, 88 USPQ2d 1385 (Fed. Circ. 2008), where the Fed. Cir. held that method claims must pass the "machine-or-transformation test" in order to be eligible for patent protection under 35 USC 101. Claims 3-5 do not past the "machine-or-transformation test" because they are not tied to a particular machine or apparatus (no machine or apparatus is recited) or does not particularly transform a particular article to a different state or thing (no transformation of a particular article is recited). The claimed method

steps recites a transformation that involves only a change in position or location of an article and the article is merely a general concept, i.e. human behavior ("orally administering...") and mental activity ("determining $^{13}CO_2$ content...").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Oren et al, U.S. Patent No. 7,338,444 B2 ("Ben-Oren"), in view of Katzman et al, U.S. Patent No. 6,186,958 B1 ("Katzman").

Claim 3: Ben-Oren teaches the following:

A method for determining gastric emptying (see Abstract) comprising

determining $^{13}CO_2$ content in exhaled respiratory air of a patient (see col. 3, l. 57, to col. 4, l. 51, and col. 19, ll. 61-67), followed by

orally administering to the patient free ^{13}CO-octanoic acid together with a standardized test meal, wherein the free ^{13}C-octanoic acid is in a form bound to egg yolk (see col. 3, l. 57, to col. 4, l. 51, and col. 19, ll. 61-67), followed by

determining $^{13}CO_2$ content in exhaled respiratory air of the patient (see col. 3, l. 57, to col. 4, l. 51, and col. 19, ll. 61-67).

Ben-Oren does not teach "wherein body-related conversion factors are dispensed with". However, Katzman teaches a breath analyzer for use with a method for determining gastric emptying (see col. 6, l. 52, to col. 7, l. 4), which determines $^{13}CO_2$ content in exhaled respiratory air of the patient (see col. 12, ll. 25-63, and col. 13, ll. 18-45). As Applicant has argued in the Remarks, p. 4, filed 09 September 2009, "...'how' the presently claimed method 'dispenses with body related conversion factors' is simply by not using them." Based on this reasoning, Katzman teaches the limitation

"body-related conversion factors are dispensed with" by not using them, since Katzman does not disclose using body-related conversion factors. It would have been obvious for one of ordinary skill in the art to modify Ben-Oren's determining $^{13}CO_2$ content in exhaled respiratory air of the patient in order to provide the following advantage, as suggested by Katzman, see col. 6, l. 52, to col. 7, l. 17:

> The present invention seeks to provide an improved breath test analyzer which overcomes disadvantages and drawbacks of existing analyzers, which provides accurate results on-site in times of the order of minutes, and which is capable of implementation as a low cost, low volume and weight, portable instrument. The breath analyzer of the present invention is sufficiently sensitive to enable it to continuously collect and analyze multiple samples of the patient's breath from the beginning of the test, and process the outputs in real time, such that a definitive result is obtained within a short period of time, such as of the order of a few minutes.
>
> Such a breath test analyzer is suitable for the detection of various disorders or infections of the gastro-intestinal tract, or metabolic or organ malfunctions, and since it can provide results in real time without the need to send the sample away to a special testing center or central laboratory, can be used to provide diagnostic information to the patient in the context of a single visit to a physician's office, or at any other point of care in a health care facility.
>
> In accordance with a preferred embodiment of the present invention, there is provided a breath test analyzer, including a very sensitive gas analyzer, capable of measuring the ratio of two chemically identical gases but with different molecular weights, resulting from the replacement of at least one of the atoms of the gas with the same atom but of different isotopic value. Since the isotopically labeled gas to be measured in the patient's breath may be present only in very tiny quantities, and since, in general, it has an infra-red absorption spectrum very close to that of the non-isotopically labeled gas, the gas analyzer must be capable of very high selectivity and sensitivity, to detect and measure down to the order of a few parts per million of the host gas.

5. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Oren in view of Katzman, as applied to claim 3 above, and further in view of Ghoos, GB 2360845 A ("Ghoos").

Claims 4 and 5: Ben-Oren teaches all the limitations of claim 1 as discussed above. Ben-Oren does not teach "the test meal comprises a fried egg, into which fried egg the free ^{13}CO-octanoic acid is stirred, a slice of toasting bread, 5 to 10 g of margarine or butter, and 150 ml of water or coffee", and "^{13}CO-octanoic acid is administered in an amount of about 40 mg to 100 mg".

However, Ghoos teaches the following:

a method for determining the gastric emptying (see Abstract), characterized in that the test meal comprises a fried egg, into which fried egg the free ^{13}CO-octanoic acid is stirred, a slice of toasting bread, 5 to 10 g of margarine or butter, and 150 ml of water or coffee (see p. 6), and characterized in that ^{13}CO-octanoic acid is administered in an amount of about 40 mg to 100 mg (see p. 5).

It would have been obvious for one of ordinary skill in the art to modify Ben-Oren's test meal to have the test meal taught by Ghoos because Ghoos' test meal, which considered a standardized test meal in the prior art, is within the scope of Ben-Oren's parameters for a test meal (see Ben-Oren, col. 4, ll. 20-44).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
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Examiner, Art Unit 3735
09/15/2010